

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456  CIVIL ACTION: 01-CV-12257-PBS  Judge Patti B. Saris
THIS DOCUMENT RELATES TO 01-CV-12257-PBS AND 01-CV-339	

**DEFENDANT BRISTOL-MYERS SQUIBB'S INDIVIDUAL  
MEMORANDUM IN OPPOSITION TO CLASS CERTIFICATION**  
**[REDACTED]**

Defendant Bristol-Myers Squibb Company (“BMS”)<sup>1</sup> submits this memorandum, together with the declaration of its employee, Zoltan Szabo (“Szabo Decl.”), in opposition to plaintiffs’ motion for class certification.

**Preliminary Statement**

At the March 8, 2004 hearing, this Court suggested that plaintiffs should seek to certify plaintiff classes “company by company, not some massive thing I couldn’t begin to control or manage. Each company is different. Each one may have different practices.” (March 8, 2004, Tr. 10-11.) Plaintiffs’ motion for class certification ignores that advice and proposes two classes and a subclass that not only encompass all five Track 1 defendant groups, but logically would include every defendant in this case.

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<sup>1</sup> The BMS defendants also include Oncology Therapeutics Network Corporation, a wholly-owned subsidiary of BMS, and Apothecon Inc., a subsidiary whose assets were sold by BMS to Novartis in 2001.

As demonstrated in the Track 1 defendants' joint submission in opposition to class certification, it is not possible to certify a class involving even one drug of one defendant because the "expectations" of each of the thousands, if not millions, of purchasers of that drug as to the relationship between average wholesale price ("AWP") and average sale price ("ASP") will inevitably differ from case to case. If the Court were to certify a class involving all of the drugs of one defendant identified in the Amended Master Consolidated Complaint ("AMCC"), the individual issues would increase exponentially and the manageability problems would be mind-boggling. Plaintiffs' suggestion that the Court should go a step further and certify a class involving all of the drugs of all of the defendants identified in the AMCC -- which would include more than 350 drugs with more than 3,000 NDCs -- conjures up a Sorcerer's Apprentice-like vision of a case that could never be tried.

Not only would such a case present individual issues that could never be addressed in a fashion that comports with Due Process, any individual defense would surely be lost in the confusion. BMS believes that it may have unique defenses in this case.<sup>2</sup> It submits this memorandum to apprise the Court of one of those defenses.

#### Statement of Facts

The core allegation of plaintiffs' case is that defendants "report" fictitious AWPs to industry publications such as First Databank, MediSpan and the Redbook (the "Publications"). (AMCC ¶ 3.) BMS has never reported AWPs to the Publications. (Szabo Decl. ¶ 6.) BMS reports wholesale list prices ("WLPs") to the Publications. (Id. ¶ 5.) Those WLPs are not

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<sup>2</sup> That is not to say that other defendants do not have unique defenses or even similar defenses. This case is so vast, and the allegations of the AMCC implicate so many pricing and marketing strategies that most manufacturers view as trade secrets, that it is impossible for any single defendant to comprehend the issues that could arise in a trial.

fictitious; they are the prices that appear on invoices to wholesalers for the drugs at issue in this case. (Id. ¶ 2.)

The Publications take BMS's WLPs and mark them up by 20% to 25% to create AWPs. (Szabo Decl. ¶ 6.) With one exception, BMS has never suggested the markup factor that should be applied to a WLP to arrive at an AWP. (Id.)<sup>3</sup> According to the testimony of at least one of the Publications, the manufacturers do not control the AWPs; the Publication claims that it establishes the AWPs based on surveys of wholesalers. (See Morgan Dep. Tr. 120, annexed as Exhibit A.)<sup>4</sup>

From time to time, especially if BMS faces competition from generics or from other brands in a therapeutic class, BMS will offer discounts to the customers (such as hospitals, managed care organizations and physicians) to whom the wholesalers sell BMS's products. (Szabo Decl. ¶ 4.)<sup>5</sup> In some cases, those discounts take the form of "chargebacks" – i.e., the wholesaler will sell the drug to the downstream customer at the discounted price and BMS will then pay the wholesaler the difference -- and in some cases, they take the form of "rebates" -- i.e., BMS will pay the downstream customer an amount, generally based on volume, after the original sale. (Id. n.1.) Although BMS tells the Publications that downstream customers receive discounts or rebates that are not reflected in the reported WLPs (Id. ¶ 5), consistent with industry

<sup>3</sup> That exception occurred in 1992 when BMS asked the Publications to increase the markup factor for certain oncology products. One Publication responded by increasing the markup factor; the others did not. (Id.)

<sup>4</sup> Wholesalers have list prices of their own. As plaintiffs' expert acknowledges, AWP as a technical and historical matter concerns that aspect of the distribution chain between drug wholesalers and retailers (i.e. pharmacists). In practice, AWP is used as a "starting point" or benchmark in negotiations concerning reimbursement rates for prescription drugs. (See Declaration of Raymond S. Hartman, sworn to September 3, 2004, Attachment D, at 1 n.1.)

<sup>5</sup> As a standard in the industry, BMS offers wholesalers a 2% discount if they pay within a certain period of time. (Szabo Decl. ¶ 2.)

practice (and with the practice of most industries generally), BMS does not disclose its discounts to the public generally.

Plaintiffs also contend that defendants have artificially “inflated” the reported AWPs by increasing them even though ASPs are going down. (AMCC, ¶¶ 3, 140, 161, 171.) Not only does BMS not report AWPs, but BMS usually increases its WLPs only when a drug is still protected by a patent and BMS believes that it can obtain sales at the new, higher list price. (Szabo Decl. ¶ 3.) In other words, if BMS refrained from increasing the WLP in these instances, it would be foregoing opportunities that any other reasonable business would pursue. On the other hand, once a drug is no longer protected by a patent and becomes subject to generic competition, BMS generally does not increase the WLP; rather the WLP for that drug will remain constant. (Id.)

That BMS’s reported WLP reflects actual transactions in the marketplace is further confirmed by the fact BMS has significant undiscounted sales at WLP for all of the drugs at issue in the case. (Szabo Decl. ¶ 12.) For of the BMS brand name drugs identified in the AMCC, BMS achieved sales revenues totaling to of the revenues that would have been generated during 1997-2002 if every unit of those drugs had been sold at 100% of WLP. (Id. ¶ 11.) For of the brand name drugs, revenues were to of WLP; for of the brand name drugs, revenues were and of WLP; and for the two remaining drugs identified in the AMCC -- generic drugs where competition is the stiffest -- revenues were and of WLP. (Id.)

#### Argument

Under Fed. R. Civ. P. Rule 23(b)(3), in addition to determining whether questions of law or fact common to the class members predominate, the Court must determine whether a class action is “superior to other available methods for the fair and efficient adjudication of the

controversy". This means that the Court must consider alternatives to the approach that plaintiffs have suggested for adjudicating this case. The Court should not certify the classes proposed by plaintiffs unless they have demonstrated that they are better than, and not merely good as, other methods of adjudication. See Commonwealth of P.R. v. M/V Emily S., 158 F.R.D. 9, 15-16 (D.P.R. 1994).

The class action method is not superior where the class proposed by the plaintiff will be unmanageable. See, e.g., Barreras Ruiz v. American Tobacco Co., 180 F.R.D. 194, 197-199 (D.P.R. 1998) (class determined to be unmanageable because large number of claimants would present many different issues). Where, as here, there are differences in the factual situations of each defendant, it is not appropriate to certify a multi-defendant class – especially where there is no claim that the defendants conspired with each other. See, e.g., Cohen v. Dist. of Columbia Nat'l Bank, et al., 59 F.R.D. 84, 88 (D.C.C. 1972) (directing separate trial for each defendant in class action because each defendant had significant differences in practices and policies at issue). As the Second Circuit stated in reviewing the denial of a class certification motion:

The key words of Rule 23 are "fair and efficient adjudication." This issue should not be decided in an abstract or academic manner, but rather in a practical and realistic way by a trial judge who has knowledge of the actual problems presented in the courtroom by these multi-plaintiff, multi-defendant cases. In theory and in an initial off-hand reaction, it is tempting to say: why not let everyone who asserts a somewhat related grievance come into a common arena to resolve their [sic] controversy? However, on a moment's reflection it should be apparent that the capacities of judges and jurors to absorb the factual situations thus presented are finite and courthouses are not coliseums. Illustrative of the desirability of focusing attention upon narrow issues is the increasing tendency in the criminal law to avoid as much as possible the multi-defendant trial on the theory that it is most difficult to assure "equal protection" and "due process" if the court or jury has to resolve a plethora of issues between a host of parties.

City of New York v. Int'l Pipe and Ceramics Corp., 410 F.2d. 295, 298 (2d Cir. 1969); see also Van-S-Aviation Corp. v. Louisiana Aircraft, Inc., No. 73-1871, 1974 WL 807, at \*5 (S.D. Fla. May 2, 1974) (denying class certification in multi-defendant case where “[i]f the class action were allowed, difficult problems are created for the trier of fact to fairly differentiate the liability, if any, of the different . . . defendants as to the individual members of the class.”).

Here, BMS seeks to defend this case on the ground, inter alia, that it has never reported AWPs to the Publications. It has reported WLPs, which are the actual list prices that appear on its invoices to wholesalers. It has no obligation to disclose discounts and, indeed, if it did so, that would result in fewer discounts because BMS would naturally be concerned that every customer would demand the maximum discount. (See Declaration of Eric M. Gaier, sworn to October 25, 2004, ¶ 80.)

Nor has BMS artificially “inflated” prices in any way. All of its price increases have been based on the belief that it can obtain sales at those prices. Furthermore, the data demonstrate that it has in fact obtained significant sales at WLP while a drug was on patent and that it generally does not increase WLPs after the drug loses patent protection. Plaintiffs cannot point to any conduct of BMS that -- even under plaintiffs’ theory of the case -- could constitute a fraud. Reporting actual list prices to trade publications cannot be a fraud.

If BMS is required to advance this defense in a case in which numerous other defendants are advancing their own unique defenses, it will never be heard. It will be lost in the morass of multiple defendants competing for the jury’s attention with respect to thousands of NDCs for hundreds of drugs. It is easy to see how that might help plaintiffs, but it is not the “fair and efficient” method of adjudicating a controversy that the rules require.

Just as plaintiffs should not be permitted to litigate this case on behalf of an “average” or composite class member, they should not be permitted to group all defendants into a composite defendant. There are important distinctions between and among the defendants. Due Process, as well as Rule 23(b)(3), requires that each defendant be given an opportunity to defend itself on the basis of the facts that pertain to it alone.

Conclusion

For the foregoing reasons, plaintiffs’ motion to certify a multi-defendant class (as well as their motion to certify any class), should be denied.

Dated: November 2, 2004

Respectfully submitted,

BRISTOL-MEYERS SQUIBB COMPANY,  
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**CERTIFICATE OF SERVICE**

I certify that on November 2, 2004, I caused a true and correct copy of the foregoing Memorandum in Opposition to Plaintiffs' Motion for Class Certification [Redacted] to be served on all counsel of record.

[Original signature on file with the Court]

/s/ Lyndon M. Tretter  
Lyndon M. Tretter